

Sheet 1 of 4

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	04843/117002
		Serial No.	10/740,075
		Applicant	Renshaw et al.
		Filing Date	December 17, 2003
		Group Art Unit	1623
(37 C.F.R. § 1.98(b))		IDS Filed	December 2, 2004

U.S. PATENT DOCUMENTS							
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)	
<i>He</i>	A1	4,027,017	05/31/1977	Hata et al.	_____	_____	
	A2	4,048,316	09/13/1977	Penn	_____	_____	
	A3	4,115,576	09/19/1978	Penn	_____	_____	
	A4	4,704,361	11/03/1987	Miccoli et al.	_____	_____	
	A5	5,278,176	01/11/1994	Lin	_____	_____	
	A6	5,409,946	04/25/1995	Garvey et al.	_____	_____	
	A7	5,472,958	12/05/1995	Gunn, Jr. et al.	_____	_____	
	A8	5,691,320	11/25/1997	von Borstel et al.	_____	_____	
<i>He</i>	A9	5,919,789	07/06/1999	Dyke et al.	_____	_____	
	<del>Dupl</del>	<del>5,930,050</del>	<del>09/28/1999</del>	<del>Renshaw et al.</del>	_____	_____	
	A10	6,103,703	08/15/2000	Renshaw et al.	_____	_____	
	A11	6,153,653	11/28/2000	Shashoua	_____	_____	
	A12	2002/019364	02/14/2002	Renshaw	_____	_____	
	A13	2003/220291	11/27/2003	Renshaw	_____	_____	
	A14	2004/176316	09/09/2004	Renshaw et al.	_____	_____	
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION							
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)	
<i>He</i>	B1	JP 08-183737	07/16/1996	Japan	_____	_____	
	B2	0 188647 A1	07/30/1986	EPO	_____	_____	
	B3	WO 00/06174	02/10/2000	WIPO	_____	_____	

DUPL. - Duplicate citation: see PTO-892 for citation.

EXAMINER L. E. Crane <i>LE Crane</i>	DATE CONSIDERED 03/23/2006
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	04843/117002
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	10/740,075
		Applicant	Renshaw et al.
		Filing Date	December 17, 2003
		Group Art Unit	1623
(37 C.F.R. § 1.98(b))		IDS Filed	December 2, 2004

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
C1	Agnoli et al., "Efficacy of CDPcholine in Chronic Cerebral Vascular Diseases (CCVD)," <i>Novel Biochemical, Pharmacological and Clinical Aspects of Cytidinediphosphocholine</i> Elsevier 305-315 (1985).
C2	Alvarez et al., "Double-Blind Placebo-Controlled Study with Citicoline in APOE Genotyped Alzheimer's Disease Patients. Effects on Cognitive Performance, Brain Bioelectrical Activity and Cerebral Perfusion," <i>Methods Find Exp. Clin. Pharmacol.</i> (Abstract) 21:633-644 (1999).
C3	Babb et al., "Differential Effect of CDP-choline on Brain Cytosolic Choline Levels in Younger and Older Subjects as Measured by Proton Magnetic Resonance Spectroscopy," <i>Psychopharmacology</i> 127:88-94 (1996).
C4	Boudouresques et al., "Therapeutic Conduct in Light of a Cerebral Vascular Accident and the Use of CDP-Choline," <i>International Symposium: Brain Suffering and Precursors of Phospholipids</i> pp. 1-13 (1980).
C5	Brown et al., "CNS Complications of Cocaine Abuse: Prevalence, Pathophysiology, and Neuroimaging," <i>Am. J. Roentgenol.</i> 159:137-147 (1992).
C6	Centrone et al., "Use of Citicoline In High Dosages in Acute Cerebrovascular Disease," <i>Minerva Med.</i> (English Abstract) 77:371-373 (1986).
C7	Chang et al., "Neurochemical Alterations in Asymptomatic Abstinent Cocaine Users: A Proton Magnetic Resonance Spectroscopy Study," <i>Biol. Psychiatry</i> 42:1105-1114 (1997).
C8	Christensen et al., "Abnormal Cerebral Metabolism in Polydrug Abusers During Early Withdrawal: A <sup>31</sup> P MR Spectroscopy Study," <i>Magn. Reson. Med.</i> 35:658-663 (1996).
C9	Citicoline Sodium (CDP-Choline), <i>Investigator's Brochure</i> , Revised: April 1994 by Interneuron Pharmaceuticals, Inc.
C10	Cohen et al., "Decreased Brain Choline Uptake in Older Adults, An in vivo Proton Magnetic Resonance Spectroscopy Study" <i>JAMA</i> 274:902-907 (1995).
C11	English et al., "Elevated Frontal Lobe Cytosolic Choline Levels in Minimal or Mild AIDS Dementia Complex Patients: A Proton Magnetic Resonance Spectroscopy Study," <i>Biol. Psychiatry</i> 41:500-502 (1997).
C12	Fioravanti et al., "Cytidinediphosphocholine (CDP Choline) for Cognitive and Behavioural Disturbances Associated with Chronic Cerebral Disorders in the Elderly," <i>Cochrane Database Systems</i> (Abstract) 4:CD000269 (2000).
C13	Gallai et al., "Study of the P300 and Cerebral Maps in Subjects with Multi-Infarct Dementia Treated with Cytidine," <i>Psychopharmacology</i> 103:1-5 (1991).
C14	Galletti et al., "Biochemical Rationale for the Use of CDPcholine in Traumatic Brain Injury: Pharmacokinetics of the Orally Administered Drug," <i>J. Neurol. Sci.</i> 103:S19-S25 (1991).
C15	Hoff et al., "Effects of Crack Cocaine on Neurocognitive Function," <i>Psychiatry Res.</i> 60:167-176 (1996).
EXAMINER L. E. Crane <i>[Signature]</i>	
DATE CONSIDERED 03/23/2006	
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

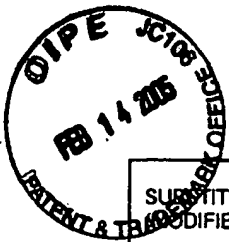
SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	04843/117002
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	10/740,075
		Applicant	Renshaw et al.
		Filing Date	December 17, 2003
		Group Art Unit	1623
(37 C.F.R. § 1.98(b))		IDS Filed	December 2, 2004

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
<i>Me</i> C16	Jacobs et al., "Cocaine Abuse: Neurovascular Complications," <i>Radiology</i> 170:223-227 (1989).
C17	Kaufman et al., "Cocaine-Induced Cerebral Vasoconstriction Detected in Humans with Magnetic Resonance Angiography," <i>JAMA</i> 279:376-380 (1998).
C18	Kreek, "Opiate and Cocaine Addictions: Challenge for Pharmacotherapies," <i>Pharmacol. Biochem. Behav.</i> 57:551-569 (1997).
C19	Levin et al., "Improved Regional Cerebral Blood Flow in Chronic Cocaine Polydrug Users Treated with Buprenorphine," <i>J. Nucl. Med.</i> 36:1211-1215 (1995).
C20	London et al., "Cerebral Glucose Utilization in Human Heroin Addicts: Case Reports from a Positron Emission Tomographic Study," <i>Res. Commun. Subst. Abuse</i> 10:141-144 (1989).
C21	Lukacsko et al., "Modulation of the Vasoconstrictor Response to Adrenergic Stimulation by Nucleosides and Nucleotides," <i>J. Pharmacol. Exp. Ther.</i> 222:344-349 (1982).
C22	Lukas et al., "Effects of Short-Term Citicoline Treatment on Acute Cocaine Intoxication and Cardiovascular Effects," <i>Psychopharmacology</i> 157:163-167 (2001).
C23	Maas et al., "Functional Magnetic Resonance Imaging of Human Brain Activation During Cue-Induced Cocaine Craving," <i>Am. J. Psychiatry</i> 155:124-126 (1998).
C24	Malec et al., "Influence of Adenosinergic Drugs on Ethanol Withdrawal Syndrome in Rats," <i>Pol. J. Pharmacol.</i> 48:583-588 (1996). (Abstract only).
C25	McCance, "Overview of Potential Treatment Medications for Cocaine Dependence," <i>NIDA Res. Monogr.</i> 175:36-72 (1997).
C26	Moglia et al., "Citicoline in Patients with Chronic Cerebrovascular Diseases (CCVD): Quantitative EEG Study," <i>Curr. Ther. Res.</i> 36:309-313 (1984).
C27	Monticone et al., "On the Therapeutic Use of Nucleosides, Cytidine and Uridine, in some Neurological Diseases," <i>Minerva Med.</i> 57:4348-4352 (1966). (plus PubMed Abstract).
C28	O'Rourke et al., "Effect of Chronic Cocaine Exposure on Carotid Artery Reactivity in Neonatal Rabbits," <i>Life Sci.</i> 59:119-130 (1996).
C29	Page et al., "Developmental Disorder Associated with Increased Cellular Nucleotidase Activity," <i>Proc. Natl. Acad. Sci. USA</i> 94:11601-11606 (1997).
C30	Peterson et al., "Neurovascular Complications of Cocaine Abuse," <i>J. Neuropsychiatry Clin. Neurosci.</i> 3:143-149 (1991).
<i>McC</i> C31	Radulovacki et al., "Adenosine Analogs and Sleep in Rats," <i>J. Pharmacol. Exp. Ther.</i> 228:268-274 (1984).
EXAMINER L. E. Crane <i>L. E. Crane</i>	DATE CONSIDERED 03/23/2006
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	04843/117002
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	10/740,075
		Applicant	Renshaw et al.
		Filing Date	December 17, 2003
		Group Art Unit	1623
(37 C.F.R. § 1.98(b))		IDS Filed	December 2, 2004

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
<i>Alc</i> C32	Renshaw et al., "Short-term Treatment with Citicoline (CDP-choline) Attenuates some Measures of Craving in Cocaine-Dependent Subjects: A Preliminary Report," <i>Psychopharmacology</i> 142:132-138 (1999).
C33	Saligaut et al., "Circling Behaviour in Rats with Unilateral Lesions of the Nigrostriatum Induced by 6 - Hydroxydopamine: Changes Induced by Oral Administration of Cytidine-5'- Diphosphocholine," <i>Neuropharmacology</i> 26:1315-1319 (1987).
C34	Salvadorini et al., "Clinical Evaluation of CDP-choline (NICHOLIN®): Efficacy as Antidepressant Treatment," <i>Curr. Ther. Res.</i> 18:513-520 (1975).
C35	Satoh et al., "Involvement of Adenosine A <sub>2A</sub> Receptor in Sleep Promotion," <i>Eur. J. Pharmacol.</i> 351:155-162 (1998).
C36	Scammell et al., "An Adenosine A <sub>2A</sub> Agonist Increases Sleep and Induces Fos in Ventrolateral Preoptic Neurons," <i>Neuroscience</i> . 107:653-663 (2001).
C37	Secades et al., "CDP-Choline: Pharmacological and Clinical Review," <i>Meth. Find. Exp. Clin. Pharmacol.</i> 17(Suppl. B):1-54 (1995).
C38	Self, et al., "Opposite Modulation of Cocaine-Seeking Behavior by D <sub>1</sub> - and D <sub>2</sub> -like Dopamine Receptor Agonists," <i>Science</i> 271:1586-1589 (1996).
C39	Shekim et al., "S-Adenosyl-L-Methionine (SAM) in Adults with ADHD, RS: Preliminary Results from an Open Trial," <i>Psychopharmacol. Bull.</i> 26:249-253 (1990).
C40	Sholar et al., "Concurrent Pharmacokinetic Analysis of Plasma Cocaine and Adrenocorticotrophic Hormone in Men," <i>J. Clin. Endocrinol. Metab.</i> 83:966-968 (1998).
C41	Tazaki et al., "Treatment of Acute Cerebral Infarction with a Choline Precursor in a Multicenter Double-Blind Placebo-Controlled Study," <i>Stroke</i> 19:211-216 (1988).
C42	Teoh et al., "Acute Interactions of Buprenorphine with Intravenous Cocaine and Morphine: An Investigational New Drug Phase I Safety Evaluation," <i>J. Clin. Psychopharmacol.</i> 13:87-99 (1993).
C43	Tomos et al., "Effect of Oral CDP-Choline on Experimental Withdrawal Syndrome," <i>Arzneim.-Forsch./Drug Res.</i> 33:1018-1021 (1983).
C44	Warner et al., "Pharmacotherapy for Opioid and Cocaine Abuse," <i>Med. Clin. North Am.</i> 81:909-925 (1997).
C45	Weiss, "Metabolism and Actions of CDP-Choline as an Endogenous Compound and Administered Exogenously as Citicoline," <i>Life Sci.</i> 58:637-660 (1995).
<i>Mc</i> C46	Wurtman et al., "Effect of Oral CDP-choline on Plasma Choline and Uridine Levels in Humans," <i>Biochem. Pharmacol.</i> 60:989-992 (2000).

EXAMINER L. E. Crane <i>L. E. Crane</i>	DATE CONSIDERED	03/23/2006
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.		

Sheet 1 of 1

SUBSTITUTE FORM PTO-1449 (REVISED 10/01/03)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Attorney Docket No. 04843/117002		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		(37 C.F.R. § 1.98(b))		Serial No. 10/740,075		
				Applicant Perry F. Renshaw et al.		
				Filing Date December 17, 2003		
				Group Art Unit 1623		
		IDS Filed February 10, 2005				
U.S. PATENT DOCUMENTS						
Examiner's Initials	Document Number	Issue or Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
<i>EC</i>	A15 2003/0114415 A1	06/19/03	Wurtman et al.			
FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS						
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)						
EXAMINER L. E. Crane <i>L. E. Crane</i>			DATE CONSIDERED 03/23/2006			
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.						



<p><b>MARK</b></p> <p><b>SUBSTITUTE FORM PTO-1449</b>      <b>U.S. DEPARTMENT OF COMMERCE</b>  <b>(MODIFIED)</b>                      <b>PATENT AND TRADEMARK OFFICE</b></p>	<table border="1"> <tr> <td>Attorney Docket No.</td> <td>04843/117002</td> </tr> <tr> <td>Serial No.</td> <td>10/740,075</td> </tr> <tr> <td>Applicant</td> <td>Perry F. Renshaw et al.</td> </tr> <tr> <td>Filing Date</td> <td>December 17, 2003</td> </tr> <tr> <td>Group Art Unit</td> <td>1623</td> </tr> <tr> <td>IDS Filed</td> <td>June 16, 2005</td> </tr> </table>	Attorney Docket No.	04843/117002	Serial No.	10/740,075	Applicant	Perry F. Renshaw et al.	Filing Date	December 17, 2003	Group Art Unit	1623	IDS Filed	June 16, 2005
Attorney Docket No.	04843/117002												
Serial No.	10/740,075												
Applicant	Perry F. Renshaw et al.												
Filing Date	December 17, 2003												
Group Art Unit	1623												
IDS Filed	June 16, 2005												
<p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>          (Use several sheets if necessary)</p> <p>(37 C.F.R. § 1.98(b))</p>													

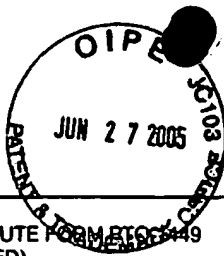
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)

[illegible]

DATE CONSIDERED 03/23/2006

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

Sheet 1 of 1

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	04843/117002
		Serial No.	10/740,075
		Applicant	Perry F. Renshaw et al.
		Filing Date	December 17, 2003
		Group Art Unit	1623
(37 C.F.R. § 1.98(b))		IDS Filed	June 22, 2005

U.S. PATENT DOCUMENTS						
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
JEC	A16 5,977,174	11/2/1999	Bradley et al.			
	A17 6,277,855	08/21/2001	Yerxa			
	A18 2002/0182196 A1	12/5/2002	McCleary			
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION						
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
JEC	B4 DE 3400276 A1	7/18/1985	Germany			
	B5 EP 0218190 A2	4/15/1987	EPO			
	B6 EP 0218190 B1	11/29/1989	EPO			
	B7 JP 63-208254	8/30/1988	Japan			
	B8 WO 99/26620	6/3/1999	WIPO			
	B9 WO 01/72288 A2	10/4/2001	WIPO			
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)						
JEC	C48	Carlezon et al., "Antidepressant-Like Effects of Cytidine in the Forced Swim Test in Rats," <i>Biol. Psychiatry</i> 51:882-889 (2002).				
	C49	Pleul et al., "Lithium Therapy and the Turnover of Phosphatidylcholine in Human Erythrocytes," <i>Euro. J. Clin. Pharmacol.</i> 31:457-462 (1986).				
	C50	Stoll et al., "Choline in the Treatment of Rapid Cycling Bipolar Disorder," <i>Biol. Psychiatry</i> 40:382-388 (1996).				

EXAMINER L. E. Crane	DATE CONSIDERED 03/23/2006
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	





Form PTO-892 U.S. Department of Commerce	Serial Number <b>10/740,075</b>	Group Art Unit <b>1623</b>	Attachment to Paper Number <b>04192006</b>	
Notice of References Cited	APPLICANT(S)			
	<b>Renshaw et al.</b>			

### Published U. S. Patent Applications

*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	Filing Date If Appropriate
	---						

### U. S. Patent Documents

*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	Filing Date If Appropriate
	---						

@ Cited herein for the first time: images are available for downloading on line at <www.uspto.gov>.

### Foreign Patent Documents


*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB- CLASS		
	---					-----	-----		

### Other References (Including Author, Title, Date, Pertinent Pages, etc.)

*	<b>R</b>	Anon. (I), "Problem Sleepiness," National Institutes of Health, NIH Publication No. 97-4071, Bethesda, MD, pages 1-4 (September, 1997). <sup>††</sup>
*	<b>S</b>	D. B., Greenberg, <sup>††</sup> "Clinical Dimensions of Fatigue," Primary Care Companion, <i>Journal of Clinical Psychiatry</i> , 4(3), 90-93 (2002).
*	<b>T</b>	Anon. (II), Search of PubMed for "cognitive function," May 16, 2005, 29 references cited on three pages. <sup>††</sup>
*	<b>U</b>	PCT Chapter I, Search report for PCT/US03/40450 derived from the same provisional US parent application (60/435,457) as the instant case, received by applicant January 28, 2005. <sup>††</sup>

† Month of publication data could not be determined from the copy in hand. Issue Number information is provided whenever possible following the volume number in parentheses.

†† Copy supplied, but apparently not cited, by applicant.

EXAMINER L. E. Crane 	DATE <b>04/18/06</b>	page 1 of 1 ¥:Reference not presently available.
*A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)		

10/740,075 PTO-892 Copy for [ ] FILE ~~IN~~ APPLICANT [ ] IFW Attchmnt to P.N. **04192006**